

Food and Drug Administration, HHS

§ 529.50

than 30 days prior to calving. Milk from treated cows must not be used for food during the first 72 hours after calving. Treated animals must not be slaughtered for food for 30 days following udder infusion.

[57 FR 37336, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992]

§ 526.1810 Pirlimycin.

(a) *Specifications.* Each 10-milliliter syringe contains 50 milligrams (mg) pirlimycin (as pirlimycin hydrochloride).

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.515 of this chapter.

(d) *Conditions of use in cattle*—(1) *Amount.* Infuse 50 mg into each infected quarter. Repeat treatment after 24 hours. Daily treatment may be repeated at 24-hour intervals for up to 8 consecutive days.

(2) *Indications for use.* For the treatment of clinical and subclinical mastitis in lactating dairy cattle associated with *Staphylococcus* species such as *Staphylococcus aureus* and *Streptococcus* species such as *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, and *Streptococcus uberis*.

(3) *Limitations.* Milk taken from animals during treatment and for 36 hours following the last treatment must not be used for food regardless of treatment duration. Following infusion twice at a 24-hour interval, treated animals must not be slaughtered for 9 days. Following any extended duration of therapy (infusion longer than twice at a 24-hour interval, up to 8 consecutive days), animals must not be slaughtered for 21 days. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 58486, Nov. 2, 1993, as amended at 65 FR 61091, Oct. 16, 2000; 73 FR 811, Jan. 4, 2008]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

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529.1660 Oxytetracycline.

529.1940 Progesterone intravaginal inserts.

529.2150 Sevoflurane.

529.2464 Ticarcillin powder.

529.2503 Tricaine methanesulfonate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.40 Albuterol.

(a) *Specifications.* A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals.* See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount.* Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use.* For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations.* Not for use in horses intended for food.

[67 FR 7072, Feb. 15, 2002]

§ 529.50 Amikacin sulfate intrauterine solution.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 250 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See No. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Two grams (8 milliliters) diluted with 200 milliliters of sterile physiological saline per day for 3 consecutive days.

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(2) *Indications for use.* For treating genital tract infections (endometritis, metritis, and pyometra) in mares when caused by susceptible organisms including *E. coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations.* For intrauterine infusion in the horse only. Not for use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 9640, Mar. 8, 1983, as amended at 53 FR 27852, July 25, 1988; 62 FR 15110, Mar. 31, 1997; 62 FR 23358, Apr. 30, 1997]

§ 529.400 Chlorhexidine tablets and suspension.

(a) *Specification.* Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.¹

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.¹

(2) *Indications for use.* For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.¹

(3) *Limitations.* Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.¹

[43 FR 10705, Feb. 23, 1979]

§ 529.469 Competitive exclusion culture.

(a) *Specifications.* Each packet of lyophilized culture contains either 2,000 or 5,000 doses in frozen pellets to be reconstituted for use.

(1) For 2,000-dose packet, add contents of one 2,000-dose packet of recon-

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

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stitution powder to 490 milliliters of deionized water. Mix. Add contents of one 2,000-dose packet of lyophilized culture. Mix thoroughly.

(2) For 5,000-dose packet, add contents of one 5,000-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 5,000-dose packet of lyophilized culture. Mix thoroughly. Allow to stand for 45 minutes before use. Use within 5 hours of reconstitution.

(b) *Sponsor.* See No. 032761 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use. Chickens*—(1) *Amount.* Apply 25 milliliters of reconstituted culture as a topical spray on each tray of 100 chicks (0.25 milliliter per chick).

(2) *Indications for use.* For early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization.

(3) *Limitations.* Administer as soon as possible after hatch, preferably at less than 1 day of age. Expose chicks to light for at least 5 minutes after spray treatment to encourage preening for oral uptake of the organisms. Provide access to feed and water as soon as possible after treatment. Do not administer antibiotics to treated chickens.

[63 FR 25164, May 7, 1998]

§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.

(a) *Specifications.* Each vaginal sponge contains 20 milligrams of flurogestone acetate.

(b) *Sponsor.* See No. 000014 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For synchronizing estrus/ovulation in cycling adult ewes during their normal breeding season.

(2) *Limitations.* Using applicator provided, insert sponge into ewe's vagina 13 days before desired start of breeding. For intravaginal use in sheep only. Do not use in young ewes that have not had lambs. Use plastic or rubber gloves when handling large numbers of sponges to minimize exposure to drug. Do not leave sponge in the vagina for more than 21 days. Ewes must not be